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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,531	07/28/2000	Stephen A. Berry	ARC2914C1	3299

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 04/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/627,531	BERRY ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of paper number 7 filed 01/08/02. Applicants can cancel claim 2 without prejudice in paper number 7 filed 01/08/02. Thus, the pending claims are 1 and 3-45.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, 17, 18 and 42-45 recite "type" and the term type is indefinite. See Ex parte Copenhaver, POBA, 1955, 109 USPQ 118-119.

Claims 1 and 3-16 are confusing because the claims while reciting non-aqueous single biocompatible vehicle also permits suspension and suspensions are not single phases. A clarification is required because the designated claims appear to have suspensions that are multi-phase.

Claim 10 recites "surfactant is gml" and "gml" is indefinite. The abbreviation "gml" appears to refer to or represent glycerol monolaurate. Applicants may overcome this rejection by replacing the abbreviation "gml" with glycerol monolaurate if that is applicants' invention.

Claim 13 contains the trademark/trade name PLURONIC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte*

Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe block copolymer and, accordingly, the identification/description is indefinite.

3. Applicant's arguments with respect to claims 1-41 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-7, 15, 22, 23, 27-29, 36 and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (US 5,374,620).

Clark discloses a growth-promoting composition. The composition comprises liquid carriers or finely divided solid carriers (column 12, lines 13 and 14). The carriers are non-aqueous vehicles (column 12, lines 20-22). The carrier contains minor amounts of ascorbic acid, low molecular weight polypeptides, proteins, polyvinylpyrrolidone, glycine, amino acids, carbohydrates, sugar alcohols and polysorbates or poloxamers or PEG (column 12, lines 24-41).

In one embodiment, the composition comprises polypropylene glycol or glycerol (column 13, lines 16-18). In example 1, Clark teaches that the pump employed to deliver the composition can be implanted to continuously deliver the composition. The teaching of Clark encompasses the scope of the claims. The mode of delivery of a composition and what the composition does is not critical in a composition claim.

6. Claims 1, 3-7, 15, 22, 23, 27-29, 36 and 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Sparks et al. (US 4,952,402).

Sparks discloses a liquid composition that can be formulated into tablets. The liquid composition comprises controlled release powder of discrete micro-particles (column 1, lines 38-43). In one embodiment the composition comprises a solution of polymer or polymers in a solvent, active ingredient dissolved or dispersed in the polymer solution (column 1, lines 44-53). In another embodiment, the composition is a controlled release antibiotic formulation in the form of powders, non-aqueous suspension of powders or reconstituted aqueous suspensions of powders (column 1, lines 55-61). The polymer could be a synthetic polymer such as polyvinylpyrrolidone (column 3, lines 15-35). Nutritional supplement such as ascorbic acid or tocopherol may be present in the composition (column 4, lines 51-53). The invention may be used as implants or ocular inserts (column 7, lines 63 and 64). A specific example comprises theophylline active ingredient, polymer, vegetable oil, glycerin and polysorbate (column 6, lines 38-54 and column 15, lines 20-25). The teachings of Sparks meet the limitations of the claims.

Applicants claim a broad composition comprising active ingredient, surfactant, polymer and a solvent. Although applicants claim a viscous vehicle, the generic claims do not recite any viscosity values. The claims are confusing because while applicants claim single-phase viscous

vehicle, the claims also allow for multiphase vehicles by permitting suspensions and dispersions. The comprising language of the generic claims does not exclude other ingredients.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3-8, 10, 12 and 15-45 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-42 of co-pending Application No. 09/497,422. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. Claims 1-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of co-pending

Application No. 09/497,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because the two applications differ in the amounts of solvent recited in claims 9 and 11 of the application and one of ordinary skill in the art would know routine experimental procedures for optimizing the solvent amounts recited in claim 9 of the co-pending application. There is no demonstration that the solvent system in the application provides unexpected result over the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

11. Claims 33-35 objected to because of the following informalities: Claim 33 depends from claims 41 or 42. A preceding claim cannot depend from a subsequent claim. Appropriate correction is required.

12. Observation:

The clause "wherein the components are not of the same type" occurs twice in claim 42.

13. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
March 21, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600